The Chemical Company

January 5, 2015

Via CDX
TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Maternal Toxicity Study in Wistar Rats with N-Vinylformamide (CASRN 13162-05-5)

Dear Section 8(e) Coordinator:

BASF is submitting results of a Maternal Toxicity Study in Wistar Rats [Crl:WI(HAN)] with N-Vinylformamide (CASRN 13162-05-5), conducted by BASF SE, Ludwigshafen, Germany. The test substance is used as a monomer.

The test substance was administered to groups of 7 female Wistar rats via gavage from gestational day (GD) 6 to 19. On day 20, all surviving rats were sacrificed, and the weights of the unopened uteri were determined. Contents of the uterus and fetuses were not examined. All rats were assessed by gross necropsy and blood examinations. Furthermore, weight and asservation of adrenal glands, kidneys, liver and spleen, as well as histopathological examination from liver of all dose groups were included

The dose levels of the test substance were 0, 10, 30, 100 and 300 mg/kg bw/d. Due to body weight loss and reduced food consumption in the animals of test group 4 (300 mg/kg bw/d) on study day GD 8, all animals were treated at a dose level of 60 mg/kg bw/d from study day GD 9 onwards.

The following is a summary of the most relevant results:

Test group 4 (300/60 mg/kg bw/d)
- Reduced food consumption (up to -67% GD 6-8)
- Reduced body weights (up to -13% on day 10) and body weight loss (-18 g GD 6-8)
- Single cell necrosis, centrilobular: 6 out of 7 females (minimal – slight)
- Necrosis, centrilobular: 2 out of 7 females (slight)
- Hypertrophy, centrilobular: 1 out of 7 females (minimal)

Test group 3 (100 mg/kg bw/d)
- Reduced food consumption (up to -38% GD 6-8)
- Reduced body weights (up to -7% on day 8) and body weight loss (-8 g GD 6-8)
- Significantly increased liver weight: absolute (114%), relative (118%)
- Single cell necrosis, centrilobular: 6 out of 7 females (minimal – slight)
- Hypertrophy, centrilobular: all females (minimal – slight)

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Test group 2 (30 mg/kg bw/d)
- No findings

Test group 1 (10 mg/kg bw/d)
- No findings

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence regarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

Technical Contact: Alisa Boucher

Alisa Boucher

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